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Title: Need to check the menace of substandard drugs.

SHRIMATI RAKSHATAI KHADSE (RAVER): There is a huge trade in substandard drugs each year. The figure for NCR Delhi alone is around Rs. 300 crore and more. As per a survey report of ASSOCHAM, every third of the drugs sold on this region are substandard. There is a need to save patients from substandard drugs. As selling sub-standard medicines called 'not of standard quality drug' would fetch the profit margin to around 25% or more while for that of standard drug this works around 5% to maximum 10%. There is no surveillance or regulatory regime in place to control this menace. Drug Inspectors are seen around for taking samples which they suppose to do secretly and surprisingly. Many a time at places, drug sellers turn into Doctors prescribing common drugs which may be a fake or substandard. Poor and common people in these cases think they have saved on the consultations fees and costly medicine. But because of the use of substandard drugs there have been a growing numbers of patients with drug-resistance tuberculosis. As the basic reason of the problem is an outdated and confused drug controlling regime in our country governed by preindependence law i.e. the Drug and Cosmetic Act 1940. Under the act, the states' regulatory bodies are authorize to issue licenses for the manufacture and sale of drugs and also to check these for quality while controlling import & export of drugs, introduction of new drug and overall supervision lies with Centre. The fund starved states neither have good laboratories nor can they hire experts to keep tabs on drug makers. The committee in 2002 headed by Dr. R. A. Mashelkar, an eminent scientist was constituted to undertake comprehensive examination of drug regulatory issues including the problems of spurious drugs. The Committee has submitted its recommendations. Through the august House, I request Hon'ble Minister to propose amendments based on these recommendations.